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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	)	
	)	
McCance, et al.	)	Art Unit: 1643
	)	
Application No. 10/511,814	)	Examiner: Harris, Alana M.
	)	
Filing Date: September 19, 2005	)	Confirmation No. 8565
	)	
For: E7 REGULATION OF P21 (CIP1) THROUGH AKT	)	

RESPONSE TO RESTRICTION REQUIREMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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Sir:

This is in response to the Office Action dated January 8, 2008, wherein restriction of the claims of the above-identified application is required. A Request for Extension of time is included herewith.

The Office Action requires restriction to one of the following two groups of claims:

Group I: Claims 1-7 and 11, drawn to a method of identifying a compound that inhibits E7 cellular proliferation activity comprising administering a compound and assaying the effect of compound using an antibody for Akt;

Group II: Claims 8, 9, and 14, drawn to a method of making a compound that inhibits E7 cellular proliferation activity comprising selecting a compound which affects the amount of Akt activity;

Group III: Claims 10 and 15, drawn to a method of identifying a compound capable of reversing the effect E7 has on Akt comprising selecting a compound which inhibits E7 maintenance of Akt activity;

Group IV: Claims 12, 13, and 16, drawn to a method of inhibiting cellular proliferation activity comprising administering an inhibitor of E7 maintenance of Akt activity;

Group V: Claims 17 and 18, drawn to a method of identifying a compound which promotes the nuclear localization of $p21^{Cip1}$ comprising assaying the effect of the compound on E7 $p21^{Cip1}$ cytoplasmic localization activity;

Group VI: Claim 19, drawn to a method of identifying an inhibitor of interaction between Akt and E7 comprising administering a compound and selecting a compound which inhibits E7 Akt interaction;

[the following were listed as Groups V to VII, respectively, but are here renumbered as Groups VII to IX]

Group VII: Claims 20-27, drawn to cell comprising a nucleic acid comprising a sequence encoding Raf;

Group VIII: Claims 28-30, drawn to a method of inhibiting aberrant cellular proliferation comprising administering a compound which inhibits E7 maintenance of Akt activity;

Group IX: Claim 31, drawn to a method of inhibiting E7 cellular proliferation activity comprising administering a compound that promotes or maintains MEK-1 activity.

As required in response to the Restriction Requirement, Applicants provisionally elect Group VI (claim 19) with traverse.

37 C.F.R. § 1.475 provides that national stage applications shall relate to one invention or to a group of inventions so linked as to form a single general inventive concept. Such inventions possess unity of invention.

The Office Action states that the inventions listed as Groups I-IX [sic] do not relate to a single general inventive concept under PCT Rule 13.1 because they allegedly lack the same or corresponding special technical features. Specifically, the Office Action posits that the method of Group I reads on a method of identifying a compound that inhibits E7 cellular proliferation

activity comprising administering a compound and assaying the effect of compound comprises using an antibody for Akt, which allegedly differs from the other method Groups in method objectives, endpoints, method steps, and parameters. Applicants respectfully disagree.

Applicants have provided that E7 promotes oncogenesis by preventing the degradation of Akt, which is a negative regulator of $p21^{Cip1}$. All of the claims are directed to methods of assaying for compounds that inhibit the activity of E7 by assaying for effects on this pathway.

For example, claims 1 and 6 (Group I) recite "identifying a compound that inhibits E7 cellular proliferation activity comprising ... assaying the effect of the compound on the amount of Akt activity in the system..." Claims 8 and 9 (Group II) similarly recite "assaying the effect of the compound on the amount of Akt activity in the system..."

These claims therefore share the same special technical feature as Group I, i.e., a compound that inhibits E7 cellular proliferation activity.

The Office Action posited that the special technical feature of Group I comprised "assaying for the effect of compound ... using an antibody." Applicants note that dependent claim 5 recites "wherein the step of assaying the effect of the compound comprises using an antibody for Akt" and that the use of antibodies for Akt is but one example of a means for assaying the amount of Akt activity.

Claims 10 and 15 (Group III), 12 and 16 (Group IV), claim 28 (Group VIII [sic]) recite "assaying the effect of the compound on E7 maintenance of Akt activity" or "a compound which inhibits E7 maintenance of Akt activity." These claims also have the same special technical feature. The difference is that these claims recite the involvement of E7 in the maintenance of the Akt activity, whereas the claims of Group I and II recite the E7 cellular proliferation activity.

Claim 19 (Group VI) recites "assaying the effect of the compound on E7-Akt interaction..." As noted above, Applicants disclosed that E7 promotes oncogenesis by binding to Akt and inhibiting its degradation. The compound of the assay is therefore a compound that inhibits E7 cellular proliferation activity, which is the special technical feature.

Claim 17 and 18 (Group V) recites "assaying the effect of the compound on E7 $p21^{Cip1}$ cytoplasmic localization activity..." As noted above, Applicants disclosed that E7 promotes oncogenesis by promoting degradation of Akt which phosphorylates $p21^{Cip1}$ in the nuclear localization signal (NLS) of $p21^{Cip1}$. The compound of the methods is therefore a compound that inhibits E7 cellular proliferation activity, which is the special technical feature.

Applicants note that all of the claims of at least Groups I-VI and VIII relate to the special technical feature a compound that inhibits E7 cellular proliferation activity. MPEP 1850 states that "[w]hether or not any particular technical feature makes a "contribution" over the prior art, and therefore constitutes a "special technical feature," should be considered with respect to novelty and inventive step." Applicants respectfully point out that the Examiner has not provided any evidence that any disclosure exists in the art that would destroy the novelty or inventive step of this common technical feature and thereby destroy the single inventive concept. Thus, the Examiner has not met the burden for establishing a lack of unity of invention and the restriction is improper.

Applicants also traverse the restriction requirement as currently set forth for the following reasons. To be valid, a restriction requirement must establish both that (1) the "inventions" are either independent or distinct, and (2) that examination of more than one of the "inventions" would constitute a burden to the Examiner. Applicants note that the restriction requirement does

not provide sufficient basis to indicate that examination of more than one of the "inventions" would overly burden the Examiner. Accordingly, for this additional reason, there is no basis for maintaining the restriction requirement.

Favorable consideration of claims 1-19, 28-30 is earnestly solicited.

A Credit Card Payment authorizing payment in the amount of $1,115.00, representing the fee for a small entity under 37 C.F.R. § 1.17(a)(5) for a Five Month Extension of Time, and a Request for Extension of Time are hereby enclosed. This amount is believed to be correct; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

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